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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,265	06/29/2007	Esben Strobech	P69471US1	4798

136 7590 05/20/2011

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EXAMINER	
REDDY, SATHAVARAM I	

ART UNIT	PAPER NUMBER
1785	

MAIL DATE	DELIVERY MODE
05/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,265	STROBECH ET AL.	
	Examiner	Art Unit	
	SATHAVARAM I. REDDY	1785	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/8/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16, 18-28 and 31-33* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 18-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Comments

1. Applicants' response filed on 3/8/2011 has been fully considered. Claims 31-33 are new, claims 22-28 are amended, claims 17, 29 and 30 are cancelled, claims 14-16 and 18-28 are withdrawn and claims 1-16, 18-28 and 31-33 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 7-13 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 3,941,133).

Regarding claim 1, Chen (US 3,941,133) discloses an absorbing element comprising an elastomeric matrix with hydrocolloids having adhesive properties (col. 2, lines 30-36) wherein the first facade of the absorbing element comprises grottos (col. 3, lines 16-18). The raised ridges #17 creates the grottos or depressions #18 as seen in Fig. 1.

Chen (US 3,941,133) does not appear to disclose the absorbing element comprising each grotto having a minimum diameter of 5 µm and the average diameter of the plurality of grottos being less than 300 µm.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the minimum diameter of each grotto to 5 µm and the average diameter of the plurality of grottos to be less than 300 µm in order to allow for a stoma bag to hold the weight of the bag and allow easy removal of the bag ((col. 1, lines 36-40) of Chen (US 3,941,133)) for the intended application, and this is supported by MPEP 2144.05(II)(A).

> "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.).

Regarding claims 2 and 3, the grottos being obtained by heat treatment or heating of the absorbing element is a process limitation in a product claim.

"Even though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (In re Thorpe, 227 USPQ 964,966) Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

Regarding claim 4, Chen (US 3,941,133) discloses the absorbing element comprising of a pressure sensitive adhesive (col. 2, lines 30-36).

Regarding claim 5, Chen (US 3,941,133) discloses the absorbing element comprising the first façade being adapted for releasable adhesion (col. 2, lines 30-36).

The first façade being adapted for releasable adhesion is also an intended use limitation.

The limitation(s) “adapted for releasable adhesion” is (an) intended use limitation(s) and is not further limiting in so far as the structure of the product is concerned. Note that “in apparatus, article, and composition claims, intended use must result in a ***structural difference*** between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. ***If the prior art structure is capable of performing the intended use, then it meets the claim***. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art." [emphasis added] *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). See MPEP § 2111.02.

Regarding claim 7, Chen (US 3,941,133) discloses the absorbing element comprising tacky elastomeric matrix (it is well established that the elastomeric matrix is self-adhesive) (col. 2, lines 30-36).

Regarding claim 8, Chen (US 3,941,133) discloses the absorbing element comprising the elastomeric matrix being a rubbery elastomeric base (col. 2, lines 30-36). The elastomeric matrix is rubbery in that it is deformable.

Regarding claim 9, Chen (US 3,941,133) discloses the absorbing element comprising the elastomeric matrix not flowing at room temperature (col. 2, lines 30-36).

Regarding claim 10, the grottos being obtained by heat treatment of the first façade of the absorbing element with electromagnetic radiation with a wavelength of more than 400 nm is a process limitation in a product claim.

Regarding claim 11, the grottos being obtained by heat treatment comprising irradiation of the first faced with an infrared laser is a process limitation in a product claim.

Regarding claim 12, Chen (US 3,941,133) does not appear to disclose the absorbing element comprising the average diameter of the grottos being less than 200 µm.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the average diameter of the grottos to be less than 200 µm in order to allow for a stoma bag to hold the weight of the bag and allow easy removal of the bag ((col. 1, lines 36-40) of Chen (US 3,941,133)) for the intended application, and this is supported by MPEP 2144.05(II)(A).

> "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.).

Regarding claim 13, Chen (US 3,941,133) discloses the absorbing element being part of a medical device such as a stomal device (col. 2, lines 30-36).

Regarding claim 31, Chen (US 3,941,133) discloses the absorbing element comprising the first faced with the grottos being part of a skin contacting surface of the absorbing element (Fig. 6; col. 3, lines 5-10; col. 3, line 60-col. 4, line 3).

The stomal bag #30 in Chen (US 3,941,133) is attached to the adhesive face plate #31which is opposite the grottos as seen in Fig. 6. The peristomal cover #11 which has the grottos is attached to the other side of the adhesive face plate and is attached to the skin.

Regarding claim 32, the grottos being configured to reduce peel adhesion by decreasing an adhesive surface area in contact with the skin is an intended use limitation as stated above.

Regarding claim 33, the grottos having a different surface property as compared with the remainder of the first façade where the different surface property is being produced by heat treatment is a process limitation in a product claim as stated above.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 3,941,133) in view of Lipman (US 6,326,421).

Chen (US 3,941,133) is relied upon as described above.

Chen (US 3,941,133) does not appear to explicitly disclose the absorbing element comprising a hydrocolloid such as guar gum.

However, Lipman (US 6,326,421) discloses the absorbing element comprising a hydrocolloid such as guar gum (col. 5, line 66-col. 6, line 18).

Chen (US 3,941,133) and Lipman (US 6,326,421) are analogous art because they are from the same field of absorbing elements.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chen (US 3,941,133) and Lipman (US 6,326,421) before him or her, to modify the absorbing element of Chen (US 3,941,133) to include the hydrocolloid of guar gum of Lipman (US 6,326,421) in that having a pressure sensitive adhesive with hydrocolloids such as guar gum provides dual attributes of being inherently absorbent and inherently adhesive ((col. 1, lines 16-22) of Lipman (US 6,326,421)).

Response to Arguments

5. Applicant's arguments, see page 14, filed 3/8/2011, with respect to the objection of the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn.

6. Applicant's arguments filed 3/8/2011 have been fully considered but they are not persuasive.

Applicants argue that Chen (US 3,941,133) does not disclose or suggest the structure of claim 1 and the required purpose of the grottos to better access for water to reach the hydrocolloids.

The Examiner disagrees and notes that Chen (US 3,941,133) discloses an absorbing element comprising an elastomeric matrix with hydrocolloids having adhesive properties (col. 2, lines 30-36) wherein the first facade of the absorbing element comprises grottos (col. 3, lines 16-18). The raised ridges #17 creates the grottos or depressions #18 as seen in Fig. 1.

Chen (US 3,941,133) does not appear to disclose the absorbing element comprising each grotto having a minimum diameter of 5 µm and the average diameter of the plurality of grottos being less than 300 µm.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the minimum diameter of each grotto to 5 µm and the average diameter of the plurality of grottos to be less than 300 µm in order to allow for a stoma bag to hold the weight of the bag and allow easy removal of the bag ((col. 1, lines

36-40) of Chen (US 3,941,133)) for the intended application, and this is supported by MPEP 2144.05(II)(A).

> "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.).

The purpose of the grottos to better access for water to reach the hydrocolloids is intended use and does not impart structure to the absorbing element. A different purpose for the grottos in the present invention than in Chen (US 3,941,133) does not mean that Chen (US 3,941,133) does not disclose the absorbing element of claim 1. Chen (US 3,941,133) discloses the absorbing element of claim 1 as stated above.

Applicants argue that Chen (US 3,941,133) has grottos opposite the skin contacting surface.

The Examiner disagrees and notes that the stomal bag #30 in Chen (US 3,941,133) is attached to the adhesive face plate #31 which is opposite the grottos as seen in Fig. 6. The peristomal cover #11 which has the grottos is attached to the other side of the adhesive face plate and is attached to the skin (Fig. 6; col. 3, lines 5-10; col. 3, line 60-col. 4, line 3).

Applicants argue that the adhesive member #13 of Chen (US 3,941,133) does not have grottos.

The Examiner notes that claim 1 requires hydrocolloids in an elastomeric matrix where a part of the first façade has grottos. Chen (US 3,941,133) discloses the adhesive member #13 having hydrocolloids in an elastomeric matrix and on one side it has raised ridges #17.

Applicants argue that Chen (US 3,941,133) does not disclose new claims 31-33.

The Examiner disagrees and notes that in regard to claim 31, Chen (US 3,941,133) discloses the absorbing element comprising the first faced with the grottos being part of a skin contacting surface of the absorbing element (Fig. 6; col. 3, lines 5-10; col. 3, line 60-col. 4, line 3).

The stomal bag #30 in Chen (US 3,941,133) is attached to the adhesive face plate #31which is opposite the grottos as seen in Fig. 6. The peristomal cover #11 which has the grottos is attached to the other side of the adhesive face plate and is attached to the skin.

Regarding claim 32, the grottos being configured to reduce peel adhesion by decreasing an adhesive surface area in contact with the skin is an intended use limitation as stated above.

Regarding claim 33, the grottos having a different surface property as compared with the remainder of the first façade where the different surface property is being produced by heat treatment is a process limitation in a product claim as stated above.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATHAVARAM I. REDDY whose telephone number is (571)270-7061. The examiner can normally be reached on 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on (571) 272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Betelhem Shewareged/
Primary Examiner, Art Unit 1785

SATHAVARAM I REDDY
Examiner
Art Unit 1785